

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of

Applicants : Victor A. Raul et al.  
Serial No. : 10/576,991  
Filed : March 6, 2007  
Title : **CONTROLLED-RELEASE COMPOSITION FOR TOPICAL  
APPLICATION AND A METHOD OF DELIVERING AN ACTIVE  
AGENT TO A SUBSTRATE**  
Docket : DOC 0170 PA (40218.354)  
Art Unit : 1627  
Examiner : S. Pihonak  
Confirm. No. : 5824

**EFS Web Electronic Submission**

**September 8, 2010**

**MAIL STOP PRE-APPEAL**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

**PRE-APPEAL BRIEF REQUEST FOR REVIEW**

Applicants request review of the final rejection mailed May 10, 2010, in the above-identified application. No amendments are being filed with this Request. This Request is being filed with a Notice of Appeal and a Request for a one-month extension of time in which to respond to the final rejection. Review is requested for the reasons stated below.

The present status of claims is: claims 1-41 are pending. Of these, claims 8, 13, and 18-41 stand withdrawn from consideration. Claims 1-7, 9-12, and 14-18 stand rejected under 35 USC §103 as unpatentable over Kosal, U.S. Patent No. 6,545,086 in view of Gray et al., U.S. Patent No. 6,040,307, and further in view of Ulrich, U.S. Patent No. 6,365,146. Applicants filed a Response to Office Action (Final Rejection) on July 6, 2010. In the Advisory Action mailed July 27, 2010, the Examiner entered the Response, but maintained the rejection of claims 1-7, 9-12, and 14-18.

Applicants submit that the rejection is not well taken in that: clear errors of fact have been made; and clear deficiencies in the references omit one or more essential elements of the claimed invention needed to establish a prima facie case. Applicants will discuss each deficiency in the rejection in turn.

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***Errors of Fact and Law***

In the Final Rejection, pages 2-3, the Examiner asserted that,

Kosal teaches a volatile silicon [sic, silicone] fluid; while it is acknowledged that some silicone fluids are lipophilic, there are others that are non-lipophilic. Kosal broadly teaches the presence of a silicone fluid; therefore, as there are silicone fluids which are non-lipophilic, Kosal still renders the claimed invention obvious, as Kosal teaches the claimed oil-in-water emulsion comprised [of] the elected silicone component, a surfactant, and water.

Initially, the Examiner has failed to establish a factual basis for her assertion that there are volatile silicone fluids that are non-lipophilic. The volatile silicone fluids of Kosal are certainly lipophilic. See, col. 3, lines 44-55, (the volatile silicone fluids are liquids); col. 3, lines 60-65 and Examples, esp. Examples 2-4 at col. 6, lines 58-62 (the volatile silicone fluids dilute/dissolve/solvate the silicone PSA's); and col. 4, lines 24-28 (the volatile silicone fluids, blended with the silicone PSA's form the oil phase of the emulsion). Kosal provides no examples of volatile silicone liquids which are non-lipophilic, and neither has the Examiner. Kosal excludes only *non-silicone* lipophilic solvents (see, col. 3, lines 60-65), not all lipophilic solvents. To the contrary, Kosal teaches the necessity of using the volatile silicone liquids when forming the emulsion. These factual deficiencies undermines the basis of the rejection.

The Examiner also erred as a matter of logic, as Kosal does not "broadly" teach the presence of volatile silicone fluids that can be either lipophilic or non-lipophilic. All of the volatile silicone fluids taught by Kosal are lipophilic and must be lipophilic as they function to dissolve/solvate the silicone PSA component of the emulsion. There is absolutely no teaching in Kosal that there is such a thing as a non-lipophilic volatile silicone fluid, let alone that such a compound could be substituted for the lipophilic silicone fluids used therein. As the disperse silicone phase of Kosal is the oil phase of the emulsion, one would not (and probably could not) use a non-lipophilic solvent in the oil phase to dissolve/solvate the silicone PSA's. This error in logic also undermines the factual basis of the rejection.

As previously argued, Kosal's *silence* concerning non-lipophilic solvents also cannot form the factual basis to support a conclusion of obviousness. *In re Burt*, 148 USPQ 548, 553

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(CCPA 1966) ("Silence in a reference is hardly a proper substitute for an adequate disclosure of facts from which a conclusion of obviousness may justifiably follow.")

Finally, the Examiner's legal conclusion that Kosal "teaches" the claimed oil-in-water emulsion is flawed in that the oil phase contains the volatile silicone fluid which was used to dissolve/solvate the silicone PSA. The Examiner's implication that Kosal's pressure sensitive silicone adhesive and volatile silicone liquid together make up the recited "silicone component," still ignores that fact that the volatile silicone liquid is necessary to form the emulsion and that its presence means that Kosal's emulsion is *not* "substantially free of lipophilic solvent" as claimed. Kosal's oil-in-water emulsion does contain a lipophilic solvent -- namely, the volatile silicone fluid. Thus, Kosal does not "teach" the claimed composition.

***Clear deficiencies in the references omit one or more essential elements of the claimed invention needed to establish a prima facie case.***

Gray and Ulrich are applied in the rejection for only limited purposes. Gray is alleged to teach the topical administration of a fungicide active agent, and Ulrich is alleged to teach that surfactants "are commonly used for drug delivery." Neither Gray nor Ulrich teach or suggest an oil-in-water emulsion that is substantially free of lipophilic solvents as claimed. Thus, the secondary references do not aid the Examiner in establishing this necessary factual support for the rejection. As discussed in detail above, Kosal also does not teach or suggest this recited element of the claims. Accordingly, as there are clear deficiencies in all of the applied references as they fail to teach a recited claim element, the rejection is not factually supported and no prima facie case for obviousness has been established.

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***Conclusion***

For all of the above reasons, applicants submit that the rejection is not well taken, is based on factual and/or legal errors and omissions, and should be withdrawn.

Respectfully submitted,  
DINSMORE & SHOHL LLP

By /Timothy W. Hagan/  
Timothy W. Hagan  
Registration No. 29,001

One Dayton Centre  
One South Main Street, Suite 1300  
Dayton, Ohio 45402-2023  
(937) 449-6400  
Facsimile: (937) 449-6405  
E-mail: [tim.hagan@dinslaw.com](mailto:tim.hagan@dinslaw.com)  
TWH/

<b>PRE-APPEAL BRIEF REQUEST FOR REVIEW</b>		Docket Number (Optional)  DOC 0170 PA/40218.354													
<p>I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)]</p> <p>on <u>September 8, 2010</u></p> <p>Signature <u>/Timothy W. Hagan/</u></p> <p>Typed or printed name <u>Timothy W. Hagan</u></p>		<table border="1" style="width: 100%; border-collapse: collapse;"><tr><td style="width: 50%; padding: 2px;">Application Number</td><td style="width: 50%; padding: 2px;">Filed</td></tr><tr><td style="padding: 2px;">10/576,991</td><td style="padding: 2px;">March 6, 2007</td></tr><tr><td colspan="2" style="padding: 2px;">First Named Inventor</td></tr><tr><td colspan="2" style="padding: 2px;">Victor A. Raul, et al.</td></tr><tr><td style="padding: 2px;">Art Unit</td><td style="padding: 2px;">Examiner</td></tr><tr><td style="padding: 2px;">1627</td><td style="padding: 2px;">S. Pihonak</td></tr></table>		Application Number	Filed	10/576,991	March 6, 2007	First Named Inventor		Victor A. Raul, et al.		Art Unit	Examiner	1627	S. Pihonak
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<p>I am the</p> <table style="width: 100%;"><tr><td style="width: 50%; vertical-align: top;"><p><input type="checkbox"/> applicant/inventor.</p><p><input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)</p><p><input checked="" type="checkbox"/> attorney or agent of record. Registration number <u>29,001</u></p><p><input type="checkbox"/> attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____</p></td><td style="width: 50%; vertical-align: top; padding-left: 20px;"><p><u>/Timothy W. Hagan/</u> _____ Signature</p><p><u>Timothy W. Hagan</u> _____ Typed or printed name</p><p><u>937-449-6400</u> _____ Telephone number</p><p><u>September 8, 2010</u> _____ Date</p></td></tr></table>		<p><input type="checkbox"/> applicant/inventor.</p> <p><input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)</p> <p><input checked="" type="checkbox"/> attorney or agent of record. Registration number <u>29,001</u></p> <p><input type="checkbox"/> attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____</p>	<p><u>/Timothy W. Hagan/</u> _____ Signature</p> <p><u>Timothy W. Hagan</u> _____ Typed or printed name</p> <p><u>937-449-6400</u> _____ Telephone number</p> <p><u>September 8, 2010</u> _____ Date</p>												
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<p>NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.</p>															
<p><input checked="" type="checkbox"/> *Total of <u>1</u> forms are submitted.</p>															

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